MAR 12 2002

## 510(K) SUMMARY

K020485

**Submitted by:**

Mary Konkowski
Senior Regulatory Affairs Associate
Baxter Healthcare Corporation
Medication Delivery Division, Regulatory Affairs
Route 120 and Wilson Road
Round Lake, IL 60073

**Proposed Device:**

All-In-One® Two Chamber Container

**Predicate Device:**

All-In-One® Two Chamber Container, cleared under premarket notification K945193, May 12, 1995

**Device Description and Statement of Intended Use:**

The All-In-One® Two Chamber Container is intended for the compounding, storage, and administration of total parenteral nutrition (TPN) solutions.

The All-In-One® Two Chamber Container is a sterile non-invasive fluid container used for compounding, storage and administration of total parenteral nutrition (TPN) solutions. It is an empty single use, disposable I.V. container that is vertically divided into two chambers. The left chamber is intended to store lipid emulsions. The right chamber is intended to store amino acid/dextrose admixtures. Additives may be added via the non-latex medication injection port located at the bottom of the left chamber. The chambers are designed to be filled with a total parenteral nutrition (TPN) solution by a pharmacy operation.

The contents of the container are intended to be stored with the seal intact (i.e., not broken) until the time of use (administration to the patient).

At the time of use, the contents of the two chambers are combined/mixed by opening the vertical peel-seal that runs along the inside of the container. The mixed contents of the container are then dispensed to the patient though a secondary administration set (i.e., a separate medical device that is not the subject of this submission).

**Summary of Technological Characteristics of New Device to Predicate Device**

The technological characteristics of the modified All-In-One® Two Chamber Container do not differ significantly from the currently marketed All-In-One® Two Chamber Container. The devices utilize the same fundamental scientific technology and have the same intended use.

**Discussion of Non-Clinical Tests; Conclusions Drawn from Nonclinical Tests**

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2002

Ms. Mary Konkowski
Senior Regulatory Affairs Associate
Baxter Healthcare Corporation
Rt. 120 & Wilson Road
Round Lake, Illinois 60073

Re: K020485
Trade/Device Name: All-In-One® Two Chamber Container
Regulation Number: 880.5025
Regulation Name: I.V. Container
Regulatory Class: II
Product Code: KPE
Dated: February 11, 2002
Received: February 13, 2002

Dear Ms. Konkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

**Device Trade Name:** All-In-One® Two Chamber Container

**Indication for Use:** The All-In-One® Two Chamber Container is intended for the compounding, storage, and administration of total parenteral nutrition (TPN) solutions.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020485